Remarks

Applicants have carefully read the Office Action of October 24, 2006, in which claims 32-52 are pending, claims 47-52 are withdrawn from consideration, and claims 32-46 were rejected. Favorably consideration is respectfully requested.

Claim Rejection—35 U.S.C. § 112, ¶ 2

Claims 32-40 were rejected under 35 U.S.C. § 112, ¶ 2 as lacking antecedent basis for "the catheter shaft" in claim 32. Claim 32 has been amended to correct these informatilities. Claim 44 was amended to correct similar informalities. Applicants therefore request the withdrawal of this rejection.

Claim Rejection—35 U.S.C. § 103

Claims 32-46 were rejected under 35 U.S.C. §103(a) as being unpatentable over Gray (WO 99/22673) in view of Patel (U.S. Patent No. 4,832,028). Applicants respectfully traverse the rejection.

Amended claim 1 recites "wherein the balloon and the outer catheter shaft are configured to stop fluid from outside the outer catheter shaft proximal to the balloon from flowing distally past the balloon when the balloon is expanded." Gray if modified, by Patel does not disclose such a claim element. Patel teaches a guiding catheter having an inflatable balloon near its tip for engaging the inner surface of the coronary lumen and a side hole for perfusion of blood through the guiding catheter while the balloon on the guiding catheter is inflated. Abstract. Patel teaches that "[b]lood is perfused through the side hole 27 and the tip 21 of the guiding catheter into the main coronary 19" and is "thus not restricted by the inflated balloon 25 on the guiding catheter 11." 2:65-68. The balloon on the guiding catheter "locks the guiding catheter 11 into place."

In contrast, the claimed invention is directed to a medical device that can stop blood flow when the balloon is inflated. Thus when other therapeutic devices such as stent delivery balloons or embolic protection filters are advanced through the guide catheter and through or past the region of interest, loose embolic material is not carried distally by the blood flow. Perfusion may be done through the first catheter shaft or another catheter shaft and is thus controlled and may be started or stopped at the discretion of the doctor. As Gray in view of Patel do not disclose a balloon coupled to the distal region of a catheter shaft and configured as claimed, applicants respectfully submit that for at least this reason claim 32 is in condition for allowance. Independent claim 41 has been amended to recite a similar limitation, "wherein the balloon and the outer catheter shaft are configured to stop fluid from outside the outer catheter shaft proximal to the balloon blood from flowing distally past the balloon when the balloon is expanded;" therefore, for at least the reasons discussed above with respect to claim 32, applicants submit that this claim is in condition for allowance. Claims 33-40 and 42-46 depend from one of claims 32 and 41 and contain additional elements; for at least this reason, applicants respectfully submit that these claims are likewise in condition for allowance.

Claims 32-46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Garza et al. (U.S. Patent No. 4,665,918) in view of Hawkins, Jr. et al. (4,790,812) and Patel. Applicants respectfully traverse this rejection.

The examiner first suggests that it would have been obvious to include a filter as taught by Hawkins, Jr. et al. "to obtain the advantage of capturing emboli or atheroma particles resulting from a procedure performed upstream." However, the guidewire of

Garza et al. is "conventional guidewire 12 having a 'J' bend at the distal end." 3:2-3. This guidewire is used as a conventional guidewire to advance and direct the guiding catheter. See 4:58-67. Moreover, the guidewire may be withdrawn through the catheter 18 to allow a smaller guidewire to be advanced to direct the assembly to a small diameter vessel. 5:10-14.

In contrast, the control wire 26 of Hawkins, Jr. et al. with the parachute basket 11 thereon "is advanced downstream through the stenosis inside catheter sheath 29." 4:66-67. It is advanced from the catheter sheath only when the stenosis is crossed. 5:2-5. Also, parachute basket 11 extends distally from the control wire 26 as can be seen, for example, in Figure 6.

A conventional "J" guidewire could not function as a guidewire if the parachute basket 11 of Hawkins, Jr. et al. were attached to it. The "J" would not be the distal most part of the guidewire and therefore could not guide catheters into side vessel. Similarly, with a parachute basket attached to it, one could not twist the "J" to direct it as desired. The spring wires 28 of the parachute basket spring outwardly apart and would serve to anchor the "J" and prevent it from moving laterally or torsionally. This goes to two of the elements of a prima facie case of obviousness. Because of the problems associated with putting parachute basket 11 on the "J" guidewire of Garza et al. there is no reasonable expectation of success in that one would not arrive at an embodiment that could be used. Second, because this modification would make the system of Garza et al. unsuitable for its intended purpose (the "J" guidewire could not be used as a guidewire), there is no motivation to combine these references. For at least these reasons, a prima

facie case of obviousness has not been made with respect to Garza et al. in view of Hawkins, Jr. et al.

The examiner also suggests modifying Garza et al. in view of Patel to provide a balloon coupled to the guiding catheter. However, one reading Patel would not provide such a balloon to another catheter without also providing a side port because, as Patel teaches repeatedly in a relatively short disclosure the importance of the side hole to a guidewire having an inflatable balloon: "Otherwise, the inflated balloon would obstruct the flow of blood to the coronary artery." 1:55-56. "Blood is perfused through the side hole 27 and the tip 21 of the guiding catheter 11 into the main coronary 19. Blood flow is thus not restricted by the inflated balloon 25 on the guiding catheter 11." 2:65-69. "Further, although the balloon 25 on the guiding catheter 11 contacts the inner surface of the coronary artery 19, blood flow is not restricted. Blood is perfused through the side hole 27 in the guiding catheter 11." However, if the side hole was included as one who read Patel would surely do, the device would not anticipate the invention of claim 32, which requires that "the balloon and the outer catheter shaft are configured to stop fluid from outside the outer catheter shaft proximal to the balloon blood from flowing distally past the balloon when the balloon is expanded" or the invention of claim 41 for similar reasons. Consequently, modifying Garza et al. in view of Hawkins, Jr. et al. and Patel would produce an embodiment where each and every embodiment of the claimed invention is not taught or suggested.

For at least these reasons, applicants respectfully submit that claims 32 and 41 are in condition for allowance. And at least for the reason that claims 33-40 and 42-46

depend from claims 32 or 41 and contain additional elements, applicants respectfully submit that these claims are in condition for allowance as well.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance, issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his Attorney,

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